K110418

510(k) SUMMARY

JUL 13 2011

POWDER FREE NITRILE EXAMINATION GLOVES

Submitter's Name	W.A RUBBERMATE CO., LTD
Submitter's Address	67/1 Bypass Road, Moo 4, Nongmaidaeng, A. Maung, Chonburi 20000, Tailand
Submitter's Phone Number	+662-3189442
Submitter's Fax Number	+662-3183268
Name of Contact Person	Terence Lim Sin Kooi
Date of Preparation	08 February 2011
Name of Device Trade Name : Common Name : Classification Name :	 POWDER FREE NITRILE EXAMINATION GLOVES Nitrile Examination Gloves Patient Examination Gloves
Legally Marketed Device to which Equivalency is Being Claimed	Powder Free Nitrile Examination Gloves as described in this 510 K Notification is substantially equivalent to the current Class 1 Patient Examination glove bearing the product code 80LZA (21 CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D 6319 – 10 Standard Specification for Nitrile Examination Gloves for Medical Application.
Description of the Device	Powder Free Nitrile Examination Gloves is substantially equivalent to the Class 1 patient examination glove bearing the product code

	80LZA (21 CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D 6319 – 10 Standard Specification for Nitrile Examination Gloves for Medical Application[1]. They are made from nitrile compound(dispersion of butadiene acrylonitrile copolymer. They are powder free gloves.
Intended Use of the Device	Powder Free Nitrile Examination Gloves are intended for single use for medical purposes that is worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patients.
Summary of Technological Characteristic Compared to the Predicate Device	There is no different technological characteristic. Gloves are made from nitrile compound (dispersion of butadiene acrylonitrile copolymer) and the initial products are powder free nitrile examination gloves.
Brief Description of Non-Clinical Tests	Testing performed per ASTM D 6319 – 10 Standard Specification for Nitrile Examination Gloves for Medical Application and 21 CFR 800.20. Gloves meet all the current ASTM D 6319-10. Primary skin irritation testing in the rabbit and delayed dermal contact sensitization study in the guinea pigs indicate no irritation or sensitization.
Brief description of Clinical Tests	No new clinical tests were conducted under this 510(k).
Conclusions Drawn from the Non-Clinical and Clinical Tests	Non-Clinical laboratory and animal based test data indicate that the powder free product meets all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA	Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Terence Lim Sin Kooi
Head of Regulatory Affairs
W.A Rubbermate Company, Limited
67/1 Bypass Road, Moo 4
Nongmaidaeng A. Maung Chonburi,
THAILAND 20000

JUL 13 2011

Re: K110418
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 29, 2011
Received: July 6, 2011

Dear Mr. Lim Sin Kooi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant : **W.A RUBBER MATE CO., LTD.**
4 Ramkhamhaeng 19 (Chareonploy),
Ramkhamhaeng Road, Huamark, Bangkapi,
Bangkok 10240, Thailand

510(k) Number (if known) : K110418 *

Device Name : POWDER FREE NITRILE EXAMINATION GLOVES (BLUE)

Indications For Use :

Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is intended to be worn on the hand for medical purpose to provide barrier against potentially infectious materials and other contaminants.

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter X
Per 21 CFR 801.109

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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